

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Anti-Migraine, Serotonin (5-HT1) Receptor Agonists PDL Edit
<b>First Implementation Date:</b>	June 15, 2005
<b>Proposed Date:</b>	December 17, 2020
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

**Why Issue Selected:** Migraine headache is a chronic, debilitating condition that tends to afflict young, productive, otherwise healthy people. The triptans are agents on the market indicated to abort acute migraine attacks and cluster headache (sumatriptan injection only). These agents offer selective pharmacology, established efficacy, a moderate side effect profile, and a well-established safety record. The disadvantages of these agents are their restrictions for use in the presence of cardiovascular disease and high cost.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> <li>Rizatriptan</li> <li>Sumatriptan</li> </ul>	<ul style="list-style-type: none"> <li>Almotriptan</li> <li>Amerge®</li> <li>Eletriptan</li> <li>Frova®</li> <li>Frovatriptan</li> <li>Imitrex®</li> <li>Maxalt®</li> <li>Maxalt-MLT®</li> <li>Naratriptan</li> <li>Onzetra® Xsail®</li> <li>Relpax®</li> <li>Sumatriptan/Naproxen</li> <li>Tosymra™</li> <li>Treximet®</li> <li>Zembrace™ SymTouch™</li> <li>Zolmitriptan</li> <li>Zomig® Nasal Spray/Tabs</li> <li>Zomig®- ZMT</li> </ul>

Type of Criteria:  Increased risk of ADE  
 Appropriate Indications

Preferred Drug List  
 Clinical Edit

Data Sources:  Only Administrative Databases

Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Anti-Migraine, Serotonin (5-HT<sub>1</sub>) Receptor Agonists
- Age range: All appropriate MO HealthNet participants aged 6 years and older

## Approval Criteria

- Documented diagnosis of cluster headaches AND claim is for sumatriptan injection (excluding Zembrace) **OR**
- Documented diagnosis of migraine **AND**
- Participants aged ≥ 6 years and < 12 years: rizatriptan only **OR**
- Participants aged ≥ 12 years and < 18 years:
  - Claim is for rizatriptan **OR**
  - Claim is for almotriptan, **sumatriptan/naproxen, or zolmitriptan nasal spray AND**
    - **Failure to achieve desired therapeutic outcomes with therapeutic trial of rizatriptan in the past 12 months OR**
    - **Documented ADE/ADR to rizatriptan OR**
- **Participants aged ≥ 18 years:**
  - Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents
    - Documented trial period for preferred agents **OR**
    - Documented ADE/ADR to preferred agents **OR**
  - **For long acting 5-HT<sub>1</sub> receptor agonists:**
    - **Failure to achieve desired therapeutic outcomes with therapeutic trial of naratriptan in the past 6 months AND**
    - **Failure to achieve desired therapeutic outcomes with therapeutic trial on 1 or more preferred agents in the past 6 months**
- Claim billed is within maximum monthly dosage limits (see Appendix A)

## Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met
- Requests for triptan therapy will be denied in the absence of approval criteria and under the following conditions:
  - Ischemic heart disease
  - Peripheral vascular syndromes
  - Cerebrovascular disease
  - Uncontrolled hypertension
  - Hemiplegic or basilar migraine
  - Concurrent ergot therapy
  - Concurrent MAOI therapy

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## Required Documentation

Laboratory Results:   
 MedWatch Form:

Progress Notes:   
 Other:

## Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)  
 Rule Type: PDL

## Default Approval Period

1 year

## Appendix A – Anti-Migraine, Serotonin (5-HT<sub>1</sub>) Receptor Agonists with maximum units per month

Drug Description	Generic Equivalent	Max Units Per Month
AMERGE 1 MG TABLET	NARATRIPTAN HCL	9 tabs (1 package)
AMERGE 2.5 MG TABLET	NARATRIPTAN HCL	9 tabs (1 package)
AXERT 12.5 MG TABLET (12 tab/pkg)	ALMOTRIPTAN MALATE	8 tabs
AXERT 6.25 MG TABLET (12 tab/pkg)	ALMOTRIPTAN MALATE	8 tabs
FROVA 2.5 MG TABLET	FROVATRIPTAN SUCC	9 tabs (1 package)
IMITREX 100 MG TABLET	SUMATRIPTAN SUCCINATE	9 tabs (1 package)
IMITREX 20 MG NASAL SPRAY	SUMATRIPTAN	12 units (2 boxes)
IMITREX 25 MG TABLET	SUMATRIPTAN SUCCINATE	9 tabs (1 package)
IMITREX 4 MG/0.5 ML CARTRIDGES	SUMATRIPTAN SUCCINATE	4 ml (8 carts - 4 boxes)
IMITREX 4 MG/0.5 ML PEN INJECT	SUMATRIPTAN SUCCINATE	4 ml (8 pens - 4 boxes)
IMITREX 5 MG NASAL SPRAY	SUMATRIPTAN	12 units (2 boxes)
IMITREX 50 MG TABLET	SUMATRIPTAN SUCCINATE	9 tabs (1 package)
IMITREX 6 MG/0.5 ML CARTRIDGES	SUMATRIPTAN SUCCINATE	4 ml (8 carts - 4 boxes)
IMITREX 6 MG/0.5 ML PEN INJECT	SUMATRIPTAN SUCCINATE	4 ml (8 pens - 4 boxes)
IMITREX 6 MG/0.5 ML VIAL	SUMATRIPTAN SUCCINATE	4 ml (8 vials)
MAXALT 10 MG TABLET (18 tab/pkg)	RIZATRIPTAN BENZOATE	8 tabs
MAXALT 5 MG TABLET (18 tab/pkg)	RIZATRIPTAN BENZOATE	8 tabs
MAXALT MLT 10 MG TABLET (18 tab/pkg)	RIZATRIPTAN BENZOATE	8 tabs
MAXALT MLT 5 MG TABLET (18 tab/pkg)	RIZATRIPTAN BENZOATE	8 tabs
ONZETRA XSAIL 11 MG	SUMATRIPTAN SUCCINATE	16 units (1 box)
RELPAK 20 MG TABLET	ELETRIPTAN HBR	6 tabs (1 package)
RELPAK 40 MG TABLET	ELETRIPTAN HBR	6 tabs (1 package)
SUMATRIPTAN 6 MG/0.5 ML SYRNG	SUMATRIPTAN SUCCINATE	4 ml (8 syr - 4 boxes)
SUMAVEL DOSEPRO 4 MG/0.5 ML	SUMATRIPTAN SUCCINATE	6 ml (12 pens - 2 boxes)
SUMAVEL DOSEPRO 6 MG/0.5 ML	SUMATRIPTAN SUCCINATE	6 ml (12 pens - 2 boxes)
TOSYMRA 10 MG NASAL SPRAY	SUMATRIPTAN	12 units (2 boxes)
TREXIMET 10-60 MG TABLET (9 tab/pkg)	SUMATRIPTAN/NAPROXEN	4 tabs
TREXIMET 85-500 MG TABLET	SUMATRIPTAN/NAPROXEN	9 tabs (1 package)
ZEMBRACE SYMTOUCH 3 MG/0.5 ML	SUMATRIPTAN SUCCINATE	8ml (16 units - 4 boxes)
ZOMIG 2.5 MG NASAL SPRAY	ZOLMITRIPTAN	12 units (2 boxes)
ZOMIG 2.5 MG TABLET	ZOLMITRIPTAN	6 tabs (1 package)
ZOMIG 5 MG NASAL SPRAY	ZOLMITRIPTAN	12 units (2 boxes)

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ZOMIG 5 MG TABLET	ZOLMITRIPTAN	6 tabs (1 package)
ZOMIG ZMT 2.5 MG TABLET	ZOLMITRIPTAN	6 tabs (1 package)
ZOMIG ZMT 5 MG TABLET	ZOLMITRIPTAN	6 tabs (1 package)

- Maximum monthly dose calculated at treating 4 episodes per month, 2 doses per episode: Amerge, Axert, Frova, Imitrex, Maxalt, Migranow, Onzetra Xsail, Sumavel, Tosymra, Treximet 85/500, Zembrace, Zomig Nasal
- Maximum monthly dose calculated at treating 3 episodes per month, 2 doses per episode: Relpax, Zomig tablets
- Maximum monthly dose calculated at treating 2 episodes per month, 2 doses per episode: Treximet 10/60

## References

1. Evidence-Based Medicine and Fiscal Analysis: “Serotonin Receptor Agonists (Triptans) – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; September 2020.
2. Drug Effectiveness Review Project – Drug Class Review on the Triptans. Center for Evidence-Based Policy, Oregon Health & Science University; June 2009; Evidence Scan, December 2015.
3. Evidence-Based Medicine Analysis: “Serotonin Receptor Agonists (Triptans)”, UMKC-DIC; August 2020.
4. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2019.
5. USPDI, Micromedex; 2020.
6. Drug Facts and Comparisons On-line; 2020.

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